

6836-65

8/27/2014

1/9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Joanna Holcombe
Sr. Regulatory Services Associate
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 27 2014

SUBJECT: Applications for Pesticide Label Amendments
Lonza Laundry Bacteriostat-Sanitizer EPA Reg. No. 6836-63 - Primary
Bardac 20-10, EPA Reg. No. 6836-65 - Secondary
Application Date: February 27, 2014
EPA Receipt Date: February 28, 2014

Dear Ms. Holcombe:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- To add claims for non-food contact sanitizer, laundry sanitizer and residual self-sanitizing.
- To update Storage and Disposal language
- To make minor label changes.

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently.

If you have any questions concerning this letter please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble", written over a horizontal line.

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Note to Reviewer:

[Language in brackets [AAA] is optional or interchangeable]

{Language in braces {AAA} is for informational purposes and will not appear on the final label}

BARDAC 20-10

Disinfectant – Sanitizer – Fungicide – Deodorizer
with Organic Tolerance
For Hospital, Institutional, Industrial, School, Dairy and Other Farm Use

Residual Bacteriostat and Self-Sanitizing Agent
Under Humid or Wet Contamination Conditions

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	5.0%
Dioctyl dimethyl ammonium chloride	2.0%
Didecyl dimethyl ammonium chloride	3.0%
Other Ingredients:	90.0%
Total:	100.0%

ACCEPTED

08/27/2014

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 6836-65

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See [left] [right] [side] [back] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-65
EPA Est. No. (insert EPA Establishment number here)
Net Contents (insert container size here)

[DOT Symbols]
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

MANUFACTURED BY:
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, safety glasses, or face shield), protective clothing, and protective gloves (chemical resistant or rubber gloves). Harmful if swallowed, absorbed through the skin, or inhaled. Do not breathe vapor. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

{If the container size is 5 gallons or greater, the following Environmental Hazards will be used:}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: The following is considered optional marketing language. ATCC numbers are listed on the data matrix.}

{MARKETING LANGUAGE}

BARDAC 20-10 is based on a highly active mixture of three Twin Chain quaternary ammonium compounds.

Use for disinfecting floors, walls, bathing areas, bed frames, lavatories, countertops, tables, chairs, garbage pails, bathroom fixtures and other hard nonporous surfaces.

Soiled and contaminated fabrics such as diapers, hospital and institutional linen, and athletic apparel is of major housekeeping concern, not only in hospitals, but in institutions, hotels, restaurants and schools.

Used as directed, **BARDAC 20-10** provides effective sanitization, residual bacteriostatic and self-sanitizing properties for laundered items such as diapers, hospital and institutional linens, food service linens, apparel and athletic apparel.

BARDAC 20-10 is designed for commercial and institutional laundry use by addition to the final rinse step.

For recommended solution concentration, see "Directions for Use."

BARDAC 20-10 is economical to use because it is concentrated. It should be handled with care.

{EFFICACY CLAIMS}

BARDAC 20-10 is an effective disinfectant when used as directed against:

Staphylococcus aureus
Salmonella enterica
Pseudomonas aeruginosa

BARDAC 20-10 is an effective non-food contact sanitizer when used as directed against:

Staphylococcus aureus
Enterobacter aerogenes

BARDAC 20-10 is an effective food contact sanitizer when used as directed against:

Escherichia coli
Staphylococcus aureus

BARDAC 20-10 fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances Recommendations of the U.S. Public Health Services in waters up to 400 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against *Escherichia coli* and *Staphylococcus aureus*.

8/9

BARDAC 20-10 is an effective laundry sanitizer when used as directed in waters up to 200 ppm hardness against:

Corynebacterium ammoniagenes
Escherichia coli O157:H7 [*E. coli* O157:H7]
Klebsiella pneumoniae
Listeria monocytogenes
Salmonella enterica [*Salmonella*]
Staphylococcus aureus [*Staph*]
Staphylococcus aureus – Community Associated Methicillin-Resistant [CA-MRSA]
Staphylococcus aureus – Hospital Associated Methicillin resistant [HA-MRSA]

BARDAC 20-10 provides residual self-sanitizing efficacy in the laundry rinse cycle when used as directed in waters up to 200 ppm hardness against:

Klebsiella pneumoniae
Staphylococcus aureus

For residual bacteriostatic or self-sanitizing activity, conditions of high relative humidity or wet contamination are required.

BARDAC 20-10 provides residual bacteriostatic efficacy in the laundry rinse cycle when used as directed against gram negative and/or gram positive odor causing bacteria:

Dilution Chart

Disinfection [1:146]	3½ oz. per 4 gallons of water
	[1¾ oz. per 2 gallons of water]
	[684 ppm active quat]
Non-Food Contact Sanitizer [1:128]	1 oz. per 1 gallons of water
	[781 ppm active quat]
Food Contact Sanitizer [1:682]	¾ oz. per 4 gallons of water
	[146 ppm active quat]
Fungicidal [1:146]	3½ oz. per 4 gallons of water
	[684 ppm active quat]
Laundry Sanitizer	15 oz. per 100 pounds dry fabric
	[781 ppm active quat]
Residual Bacteriostat	2.7 oz. per 100 pounds dry fabric
	[175 ppm active quat]
Residual Self Sanitization	3 oz. per 60 100 pounds dry fabric
	[195 ppm active quat]

{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DISINFECTION [IN HOSPITALS, NURSING HOMES, AND OTHER HEALTH CARE INSTITUTIONS] [DIRECTIONS]

Use 3½ oz. of **BARDAC 20-10** to 4 gallons water.

Preclean surfaces prior to disinfection. Apply appropriate amount of **BARDAC 20-10** with a cloth, mop, sponge or coarse [mechanical] spray device until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry or wipe excess liquid with cloth, sponge, or mop. Fresh solution should be prepared daily or more often if the use solution becomes visibly dirty.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

{Note to reviewer: Only one of the following two statements will be used:}

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{or}

This product is not for use on medical device surfaces.

DISINFECTION OF BARBER TOOLS (Not For Use in California)

Preclean hard nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure, and other salon/barber instruments and tools in use solution of 1¼ oz. per 2 gallons of water for 10 minutes. Rinse thoroughly and dry before use. Use a fresh product daily. Do not reuse solutions, and discard solutions if it becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS

For disinfection of poultry brooders, watering fountains, feeding equipment, and other quarters (such as stalls and kennel areas). Prior to disinfection, all poultry, other animals and their feeds must be removed from the premises, vehicles and enclosure such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 3½ oz. of **BARDAC 20-10** to 4 gallons water. Saturate surfaces with the disinfecting solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

After disinfection, ventilate buildings, coops and other closed spaces. Do not house poultry, or other animals, or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

FUNGICIDAL

At 3 ½ oz. per 4 gallons of water this product is effective against *Trichophyton mentagrophytes* [Athletes foot fungus] when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities. Follow Disinfection Directions.

TO SANITIZE NON-FOOD CONTACT SURFACES:

Add [mix] 1 oz. of **Bardac 20-10** per 1 gallon of water [1:128 dilution] to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 5 minutes. Wipe dry with a sponge, mop or cloth or allow to air dry.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD CONTACT LOCATIONS

Use for sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a solution of ¾ oz. **BARDAC 20-10** in 4 gallons of water [146 ppm active] to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least one minute [60 seconds] followed by adequate draining [and air drying]. Do not rinse.

Fresh solution should be prepared daily or more often if use solution becomes visibly dirty.

For mechanical application, use solution may not be reused for sanitizing applications but may be used for other purposes cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth, sponge or brush.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

DEODORIZATION

Apply 3 oz. per 5 1/2 gallons of water with mop, cloth, sponge, or mechanical sprayer. Thoroughly wet surfaces and allow to air dry.

COMMERCIAL AND INSTITUTIONAL LAUNDRY USES**LAUNDRY SANITIZER**

Add [mix] 15 oz. of **BARDAC 20-10** in high efficiency applications per 60 gallons of water and a maximum of 100 pounds of fabric [dry weight] to sanitize laundered fabrics in the rinse cycle. A minimum cycle time of 5 minutes is required.

RESIDUAL BACTERIOSTATIC

Initial Treatment: Use 2.7 oz. of **BARDAC 20-10** for a minimum 24 hours holding in commercial or industrial applications per a maximum total of 60 gallons [500 lbs.] of water and a maximum of 100 pounds of fabric [dry weight]. Dilute the appropriate amount of **BARDAC 20-10** in one to two gallons of water and then add this solution to the wash wheel at the beginning of the final rinse cycle. A minimum rinse cycle time of 10 minutes is required.

Repeat treatment: Follow Initial Treatment directions and re-treat fabric after each washing [or if odor persists].

RESIDUAL SELF-SANITIZING

Use 3 oz. of **BARDAC 20-10** in commercial or industrial applications per a maximum total of 60 gallons [500 lbs.] of sterile tap water and a maximum of 100 pounds of fabric [dry weight]. Dilute the appropriate amount of **BARDAC 20-10** in one to two gallons of sterile tap water and then add this solution to the wash wheel at the beginning of the final rinse cycle. A minimum rinse cycle time of 8 minutes is required.

*{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional **Dilutable** uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers}*

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

[Plastic and Metal Containers:] Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

[Metal Containers only:] DO NOT cut or weld metal containers.

[Bag in Box Containers:] Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.